

Office Action Summary

Application No. 09/442,256	Applicant(s) YIGZAW
Examiner DR. HERBERT J. LILLING	Art Unit 1651

The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ONE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Aug 24, 2001

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 4-6, 8, 9, 12-14, 22, 24-26, 29, 32, 36, 38-40, and 54-72 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 4-6, 8, 9, 12-14, 22, 24-26, 29, 32, 36, 38-40, and 54-72 are subject to restriction and/or election requirem

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

18) Interview Summary (PTO-413) Paper No(s) _____

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

20) Other

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The request filed on August 24, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/442,256 is acceptable and a CPA has been established. An action on the CPA follows.

2. Claims 4-6, 8-9, 12-14, 22, 24-26, 29, 32, 36, 38-40 and 54-72 are now pending in this instant CPA.

Claims 1-3, 7, 10-1, 15-21, 23, 27-28, 30-31, 33-35, 37 and 41-53 have been cancelled.

The previous Office action, Claims 22, 29, 36 and 38-40 were acted upon drawn to a method of producing a composition of extracts of plant material, classified in class 424, subclass 195.1. Applicant will have the opportunity to elect the same Invention or one of the other inventions as noted in the next paragraph. Applicant may consult Examiner for assistance.

3. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 4-6, 8-9, 12-14, 22, 24-26 and 38-40 , drawn to a **first method** of producing a composition comprising the formation of single extract of plant material which can be isolated or recovered by a multitude of separation steps for the single extracted product composition, classified in class 424, subclass 725+.

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- II. Claims 29,32, 36 and 54-70, drawn to a **second method** of producing a composition comprising an extract and an additional extract from one or more additional crude materials, classified in class 424, subclass 725+ depending upon the combination of the extraction materials.
- III. Claim 71, drawn to a **first product** of an extracted plant material , classified in class 424, subclass 725, depending upon the extracted material.
- IV. Claim 72, drawn to a **second product composition** of a mixture of extracts, classified in class 424, subclass 725+ depending upon the combination of extracted materials.

4. The inventions are distinct, each from the other because:

Inventions I/II and III, IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process e.g. extracts of other plants or by organic synthetic methods.

Invention I process is separate and patentably distinct from that of process Invention II as well as the products of Invention III are patentably distinct from that of product mixtures of Invention IV.

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5. Because these inventions are distinct for the reasons given above have acquired a separate status in the art because of their recognized divergent subject matter and the search required for one invention is not required for the other invention, thusly the restriction for examination purposes as indicated is proper.

6. This application contains claims directed to the following patentably distinct species of the claimed invention:

I. Whereby the composition is obtained from the group consisting of

- a. > Glinus lotoides
- b. > Ruta chalepensis
- c. > Hagenia abyssincia

or

- d. > Millettia ferruginea.
- e. > Mixtures of above-please specify the mixture (a-d).

II. Whereby the plant material is selected from the group consisting of ;

- g. Flowers
- h. Leaves
- i. Seeds
- j. Stems
- k. Mixtures thereof-please specify.

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III. Whereby extract is obtained with a solvent selected from the group consisting of

a.> organic solvents

1.> polar solvent

aa.> methanol

bb.> acetone

2.> non-polar solvent

aa.> hexane

bb.> ether

b.> the solvent is

bb1. single solvent

bb2. mixture of solvents

IV. Whereby the composition comprising:

1. One extract from one plant material
2. Two extracts from the same plant material
3. Two extracts from different plant materials-specify plants.

V. Whereby the pharmaceutical carrier is in the form of

p.> tablets

q.> capsules

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- r.> powders
- s.> suppositories
- t.> suspensions
- u.> solutions

VI. Whereby the method involves adjusting the pH of the solution with

- A. Basic material
- B. Acidic material.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

APPLICANT IS REQUIRED TO SELECT ONE SPECIES FROM EACH OF THE ABOVE GROUPS I-VI AND SUBGROUPS IF APPROPRIATE FOR THE ELECTED INVENTION AND SPECIES.

7. Applicant is advised that the reply to this requirement to be complete must include an election of the invention I-II-III or IV (as submitted in above paragraph 3) as well as elections of species as noted in the above paragraph 6) to be examined even though the requirement be traversed (37 CFR 1.143).

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 and fax number (Art Unit 1651) is (703) 308-4242, working time Mon-Thurs about 5:30 A.M.-about 3:00 P.M. or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit **1651**
September 25, 2001

Herbert J. Lilling
HERBERT J. LILLING
PATENT EXAMINER
GROUP 160 ART UNIT 1651

Attachment for PTO-948 (Rev. 03/01, or earlier)

6/18/01

The below text replaces the pre-printed text under the heading, "Information on How to Effect Drawing Changes," on the back of the PTO-948 (Rev. 03/01, or earlier) form.

REC'D 15 2001

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the Notice of Allowability. Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136(a) or (b) for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a).

Failure to take corrective action within the set period will result in **ABANDONMENT** of the application.